UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN THE MATTER OF ADMINISTRATIVE SUBPOENAS DUCES TECUM SERVED UPON MISSOURI BAPTIST MEDICAL CENTER AND MISSOURI BAPTIST HOSPITAL-SULLIVAN ON SEPTEMBER 29, 2021 COMPELLING PRODUCTION OF DOCUMENTS AND TANGLIBLE ITEMS CONCERNING DR. RAFFI KRIKOR KRIKORIAN AND/OR COMPREHENSIVE CARDIOVASCULAR CONSULTANTS.	)	Case No. 4:21-mc-01049-SEP

MEMORANDUM AND ORDER

This matter comes before the Court on the Joint Motion to Quash or Modify and for Entry of a Protective Order of Missouri Baptist Medical Center and Missouri Baptist Hospital – Sullivan. Doc. [1]. For the reasons set forth below, the Motion will be denied**.**

I. Procedural History

On September 29, 2021, pursuant to 18 U.S.C. § 3486, the United States Department of Justice (DOJ), acting through the United States Attorney's Office for the Eastern District of Missouri (USAO), issued two separate administrative subpoenas (Subpoenas) to Missouri Baptist Medical Center (MBMC) and Missouri Baptist Hospital – Sullivan (MBHS) (collectively, "the Hospitals"). The Subpoenas were issued as part of a criminal investigation into allegations that Dr. Raffi K. Krikorian (Dr. Krikorian); Comprehensive Cardiovascular Consultants (CCC), a medical group owned and operated by Dr. Krikorian; and others at Dr. Krikorian's direction had performed medically unnecessary procedures, falsified patient files and other records to justify the medical procedures, and billed health care benefit programs for medically unnecessary, up-coded, and nonrendered medical services. The Subpoenas sought seven categories of documents:

1. Contracts, agreements, or other documents reflecting understandings between MBMC and Dr. Krikorian and/or CCC concerning Dr. Krikorian's practice at MBMC;

2. Documents that reflect, refer, or relate to lawsuits or complaints by patients, family members of patients, or other patient representatives against Dr. Krikorian and/or MBMC concerning the care or services provided by Dr. Krikorian;
3. Documents that reflect, refer, or relate to complaints made against Dr. Krikorian by physicians, staff, and/or employees of MBMC or any other individuals or entities;
4. Documents, including emails, that refer or relate to billing and reimbursement issues concerning the care or services provided by Dr. Krikorian;
5. Documents, including emails, that refer or relate to the quality of care or services provided by Dr. Krikorian, as measured by credentialing requirements;
6. Documents that reflect, relate, or refer to peer reviews completed on Dr. Krikorian; and
7. Minutes of meeting, or portions thereof, where Dr. Krikorian was a topic of discussion.

After service of the Subpoenas, counsel for the Government and the Hospitals communicated concerning the information sought. *See* Doc. [6] at 2. The Hospitals objected to the requests as, among other things, overbroad and unduly burdensome. On November 18, 2021, the Government agreed to narrow the scope of the Subpoenas in the following manner. The "Instructions" section of the Subpoenas was originally directed to both MBMC and MBHS as well as "any and all related entities, including any employee, agent, contractor, officer, director, and any corporate parent, predecessor, successor, subsidiary, branch or related company or party thereof." Doc. [1-1] at 3. However, the Government agreed to delete the portion of the "Instructions" that read: "any and all related entities, including any employee, agent, contractor, officer, director, and any corporate parent, predecessor, successor, subsidiary, branch or related company or party thereof." *See* Doc. [6] at 2. Government counsel also confirmed to counsel for MBMC and MBHS that the Subpoenas did not seek any documents or information protected by the attorney-client privilege. *Id.*

On November 22, 2021, MBMC and MBHS filed the instant Motion, objecting to the "Instructions" section of the Subpoenas and each of the seven categories of documents sought by the Subpoenas. MBMC and MBHS argue that the requests are "vague and overbroad, unduly burdensome, violative of Fourth Amendment guarantees, seek[ ] confidential patient information protected from disclosure under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and privileged information protected by the Missouri Peer Review Privilege (MO. REV. STAT. § 537.035), the attorney-client privilege, the insured-insurer privilege, and/or any

other applicable privileges and exemptions." *See*, Doc. [1-5] at 3. On December 16, 2021, the Government responded in opposition to the Motion. Doc. [6]. On December 27, 2021, MBMC and MBHS filed their reply. Doc. [8]. The matter is fully briefed and ripe for resolution.

As set forth below, the Court finds that the Subpoenas do not violate the constitutional rights of MBCM and MBHS, do not seek information privileged under federal law, and comply with the requirements of 18 U.S.C. § 3486.

II. The Department of Justice Has Statutory Authority to Issue Section 3486 Administrative Subpoenas.

In August 1996, Congress passed and President William J. Clinton signed into law the Health Insurance Portability and Accountability Act (HIPAA). A portion of HIPAA, codified at 18 U.S.C. § 3486, invested DOJ with the authority to issue administrative subpoenas in specified types of criminal investigations. Section 3486 provides as follows:

> (a) Authorization.—
> (1)(A) In any investigation of—
> (i)(I) a Federal health care offense . . . the Attorney General may issue in writing and cause to be served a subpoena requiring the production and testimony described in subparagraph (B).
> (B) Except as provided in subparagraph (C), a subpoena issued under subparagraph (A) may require—
> a. the production of any records or other things relevant to the investigation; and
> b. testimony by the custodian of the things required to be produced concerning the production and authenticity of those things.

Pursuant to this statute, the Attorney General and his designees may issue administrative subpoenas to obtain records that may be relevant to the investigation of a federal health care offense. It is under this statutory authority that the Subpoenas to MBMC and MBHS were issued by DOJ.

III. Limitations on Use of § 3486 Administrative Subpoenas

Although different from grand jury subpoenas, administrative subpoenas are analogous to grand jury subpoenas due to their functional similarity as an evidence gathering tool. *See Resolution Trust Corporation v. Thornton*, 41 F.3d 1539, 1546 (D.C. Cir. 1994) (observing that an administrative agency's subpoena power is analogous to that of a grand jury). However, § 3486 administrative subpoenas differ from federal grand jury subpoenas in several respects. Section 3486 administrative subpoenas may be issued only in investigations concerning the

limited universe of federal criminal offenses identified in § 3486(a)(1)(A) (federal health care offense, federal offense involving the exploitation or abuse of children, unregistered sex offender, threat offenses in violation of §§ 871, 879 or against a person protected by the United States Secret Service). Section 3486 may be used to subpoena documents or to subpoena the testimony of document custodians concerning the production and authentication of such records or documents. Section 3486 administrative subpoenas may not otherwise be used to obtain testimony. The site designated for the production of the subpoenaed records may not be more than 500 miles from the place where the Section 3486 administrative subpoena was served. Additionally, an administrative subpoena must grant the person or entity a reasonable period of time to comply, unlike in the grand jury context, where DOJ can require immediate production of documents.

Congress enacted §3486 to facilitate health care fraud enforcement efforts after estimating that the health care dollars lost to fraud could be as high as ten percent of total health care costs. *In re subpoena Duces Tecum*, 228 F.3d 341, 346 n.1 (4th Cir. 2000) (denying motion to quash health care fraud subpoena after rejecting recipient's constitutional arguments). The statute itself, as well as related statutory history, makes clear that DOJ's subpoena power when investigating health care fraud was meant to be broad. *See*, *e.g.*, *Doe v. United States*, 253 F.3d 256, 267 (6th Cir. 2001) ("[I]t appears clear, both from the language of the statute and from Congress's intent in enacting HIPAA, that DOJ's subpoena power in investigating federal health care offenses is meant to be broad.").

IV. Delegation of Authority to Issue § 3486 Administrative Subpoenas

On August 13, 2001, the United States Attorney General delegated to each United States Attorney the authority to issue administrative subpoenas pursuant to 18 U.S.C. § 3486, and further authorized each United States Attorney to re-delegate the authority to individual Assistant United States Attorneys (AUSAs). Government counsel in the present matter has been delegated 18 U.S.C. § 3486 authority. Doc. [6] at 6.

V. Standards for Enforcement of an Administrative Subpoena

A federal agency's administrative subpoena should be enforced if (1) the subpoena was issued pursuant to lawful authority, (2) the subpoena was issued for a lawful purpose, (3) the subpoena requests information that is relevant to the lawful purpose, and (4) the disclosure sought is not unreasonable. *Fresenius Medical Care v. United States*, 526 F.3d 372, 375-6 (8th

Cir. 2008) (motion to quash § 3486 subpoena denied); *United States v. McDonnell Douglas Corp.*, 751 F.2d 220, 226 (8th Cir. 1984) (*citing United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950)). The test for enforcement is not a stringent one. "Subpoena enforcement proceedings are not intended to be exhaustive inquisitions into the practices of regulatory agencies," but instead are designed to produce a "speedy resolution" of the issues. *United States v. Medic House, Inc.*, 736 F. Supp. 1531, 1538 (W.D. Mo. 1989) (citations omitted) (administrative subpoena issued by U.S. Department of Health and Human Services).

Once the agency in question, here DOJ, demonstrates the four factors, the burden then shifts to the party seeking to quash the subpoena to demonstrate that "judicial enforcement of the subpoena would amount to an abuse of the Court's process." *E.E.O.C. v. Peat, Marwick, Mitchell & Co.*, 775 F.2d 928, 930-31 (8th Cir. 1985), *cert. denied*, 475 U.S. 1046 (1986). Demonstrating that enforcement would amount to an "abuse of the Court's process" is a "heavy burden" to bear. *Medic House*, 736 F. Supp. at 1536. Here, as further discussed below, the Government has made a sufficient showing as to each of the four factors, and MBMC and MBHS have failed to demonstrate that enforcement of the Subpoenas would amount to an abuse of the Court's process.

A. The Subpoenas Were Issued Pursuant to Lawful Authority.

Section 3486 of Title 18 of the United States Code provides the Attorney General with subpoena power to investigate "a Federal Health Care Fraud offense." 18 U.S.C. § 3486(a). In the present case, Government counsel issued the subpoena after being delegated the authority to do so. Doc. [6] at 6. The Subpoenas were issued in furtherance of a health care fraud investigation of Dr. Krikorian. MBMC and MBHS do not even contest that they were issued pursuant to lawful authority. Therefore, as MBMC and MBHS appear to concede, the Government has satisfied the first factor of the analysis.

B. The Subpoenas Were Issued For A Lawful Purpose.

"So long as the agency makes a plausible argument in support of its assertion of jurisdiction, a district court must enforce the subpoena if the information sought there is not plainly incompetent or irrelevant to any lawful purpose of the agency." *E.E.O.C. v. Kloster Cruise Ltd.*, 939 F.2d 920, 922 (11th Cir. 1991) (internal quotation removed). Those seeking to quash a Section 3486 subpoena bear a "heavy burden to disprove the existence of a valid purpose

for an administrative subpoena." *United States v. Whispering Oaks Residential Care Facility, LLC*, 673 F.3d 813, 817 (8th Cir. 2012) (citations omitted).

In the instant case, DOJ is investigating the billing practices of Dr. Krikorian. As further discussed below, the Subpoenas seek documents that clearly advance that investigation, and MBMC and MBHS do not contest that they were issued for a lawful purpose. The Subpoenas have a lawful purpose because they were issued as part of a criminal health care investigation related to the provision and reimbursement of health care benefits, items, and services. *See In re Subpoena Duces Tecum*, 228 F.3d 341, 346 n. 1 (4th Cir. 2000) (Section 3486 was enacted "to facilitate enforcement of federal statutes relating to healthcare fraud and abuse and thereby to promote the availability and affordability of health insurance in the United States."). The Government has satisfied the second factor.

C. The Subpoenas Seek Relevant Information.

MBMC and MBHS assert that the Subpoenas seek evidence that is not relevant to DOJ's investigation of Dr. Krikorian and on this basis alone should be quashed. But MBMC's and MBHS's narrow definition of "relevance" is inconsistent with applicable case law. A subpoena seeks relevant information if the materials sought are "reasonably relevant" to the agency's inquiry. *Morton Salt*, 338 U.S. at 652. As the Eighth Circuit has recognized, "[t]he standard for determining the relevance of a subpoena's requests is not particularly burdensome, and indeed, a subpoena "should be enforced when the evidence sought by the subpoena is not plainly incompetent or irrelevant to any lawful purpose of the agency in the discharge of its duties." *Whispering Oaks*, 673 F.3d at 818. "For purposes of an administrative subpoena, the notion of relevancy is a broad one. An agency can investigate merely on the suspicion that the law is being violated, or even just because it wants assurance that it is not. So long as the material touches a matter under investigation, an administrative subpoena will survive a challenge that the material is not relevant." *Equal Employment Opportunity Commission v. Elrod*, 674 F.2d 601, 613 (7th Cir. 1982) (internal citations and quotation marks omitted); *see also Doe v. United States*, 253 F.3d 256, 267 (6th Cir. 2001) (It "appears clear, both from the language of the statute and from Congress's intent in enacting HIPAA, that DOJ's subpoena power in investigating federal health care offenses is meant to be broad."). Additionally, "[t]he language of § 3486 indicates that the question of an administrative subpoena's relevance is not a question of evidentiary relevance." *Whispering Oaks*, 673 F.3d at 818, *citing Doe*, 253 F.3d at 266. The question simply is "whether

the documents requested pursuant to the subpoena are relevant to the health care fraud investigation being undertaken." *Id.* In other words, subpoenas are not limited to seeking documents that would be admissible in judicial or administrative proceedings.

In considering the relevance of the Subpoenas, this Court must necessarily view the Subpoenas in the context of the investigation from which they arose. Here, as the Government indicated in its responsive pleading, it is investigating allegations that Dr. Krikorian performed medically unnecessary procedures; falsified medical and other records to justify the procedures; billed health care benefit programs for medically unnecessary and non-rendered services; and billed for services purportedly provided by him when he was out of the country or otherwise unavailable to personally perform or supervise the service. Doc. [6] at 9. There are also allegations that patients were harmed by Dr. Krikorian's actions. In its responsive pleading, the Government outlined the relevance of each of the document requests 1-7. *Id.* at 9-12.

The Government asserts that the requested documents are relevant to vital aspects of the healthcare fraud conduct under investigation, including Dr. Krikorian's motives, his professional and financial relationship with MBMC and MBHS, the methods and amounts of his compensation from MBMC and MBHS, complaints raised against Dr. Krikorian by patients and hospital staff and employees, Dr. Krikorian's knowledge of and participation in the billing process, instances in which Dr. Krikorian performed medically unnecessary procedures, and/or instances in which Dr. Krikorian was responsible for causing patient harm. The Court agrees. It is evident that the requested documents are not "plainly incompetent or irrelevant" to the underlying investigation, and the Court finds the requested documents readily satisfy the relevance standard necessary to enforce the subpoenas. Therefore, the Government has satisfied the third factor of the analysis.

D. The Disclosures Sought Are Not Unreasonable.

Before discussing the reasonableness of the Subpoenas, the Court notes preliminarily that the Government has narrowed the scope of the Subpoenas by indicating that it does *not* seek production of documents otherwise covered by the following language: "any and all related entities, including any employee, agent, contractor, officer, director, and any corporate parent, predecessor, successor, subsidiary, branch or related company or party thereof." Doc. [6] at 2. The Government has further indicated that it does not intend to seek production of documents covered by the attorney-client privilege. *Id.* Additionally, with respect to Request No. 7, which

seeks minutes of meetings where Dr. Krikorian was a topic of discussion, the Government has modified and narrowed the request to seek meeting minutes where Dr. Krikorian's "contracts and agreements with MBMC and MBHS, quality of care, coding and billing, and compensation" were discussed with "staff responsible for monitoring, supervising, or evaluating" Dr. Krikorian's actions at the Hospitals. *Id*. at 12. Assuming those limitations, as further discussed below, the Court finds that the Subpoenas require reasonable disclosures and compliance will not be unduly burdensome.

The last factor to be considered is whether the disclosure sought is unreasonable. *Fresenius Medical Care*, 526 F.3d at 375-6. A subpoena "will be disallowed if it is 'far too sweeping in its terms to be regarded as reasonable' under the Fourth Amendment," *United States v. Calandra*, 414 U.S. 338, 346 (1974). Addressing a challenge to a Section 3486 subpoena, the Fourth Circuit has stated that for a subpoena to be reasonable, it "must be (1) authorized for a legitimate governmental purpose; (2) limited in scope to reasonably relate to and further its purpose; (3) sufficiently specific so that a lack of specificity does not render compliance unreasonably burdensome; and (4) not overly broad for the purposes of the inquiry as to be oppressive . . ." *In re Subpoena Duces Tecum*, 228 F. 3d. 341, 349-50 (4th Cir. 2000) (finding a Section 3486 subpoena request for thousands of patient files and controlled substance records reasonably related to investigation of doctor).

The Hospitals assert that the Subpoenas are overly broad and far too sweeping to be regarded as reasonable, and that compliance would be oppressive and unreasonable, and thus unduly burdensome. *See* Doc. [1-5] at 7. They also assert that the time period covered by the requests is unreasonably lengthy, and that the requests would require them to seek out documents that are not within their possession, or that are publicly available. However, MBMC and MBHS fail to indicate more precisely why or how compliance with the Subpoenas will be an undue burden. *See Whispering Oaks*, 673 F.3d at 819 (rejecting overbreadth objection to Section 3486 subpoena when company offered no reason why enforcement and compliance with subpoenas would be overly burdensome); *Doe*, 253 F.3d at 269 (enforcing administrative subpoena where individual made only "general and conclusory statements" as to undue burden of the subpoena).

Measured by the above standards, the Subpoenas are clearly reasonable. The Subpoenas here request documents that directly relate to the provider under investigation and seek a limited universe of records relating to a single provider during a reasonably restricted time frame.

First, the Subpoenas were issued during a DOJ investigation into allegations that Dr. Krikorian had committed health care fraud. Second, as described above, the Subpoenas are relevant because each request seeks information about Dr. Krikorian, the subject of the ongoing investigation. Further, the Subpoenas identify, to the extent possible, the categories or types of documents that may contain the requested information. As evident from the face of the Subpoenas, and as indicated by the Government in its responsive pleading, MBMC and MBHS are not required to produce documents not in their possession. If MBMC and MBHS do not possess responsive documents, they may simply indicate as much in their response to the subpoenas. As to MBMC and MBHS's argument that the time frame of the requested documents is so broad as to be unduly burdensome, the Court notes that the Government has limited the scope of the documents to the time frame of the conduct under investigation. "The fact that matters with respect to which discovery is sought may be time-barred by the applicable statute of limitations does not foreclose discovery," particularly because an act "beyond the period of limitations may constitute relevant background evidence in a proceeding in which a current practice is at issue." *United States ex rel. Roberts v. QHG of Ind., Inc.*, 1998 WL 1756728, at *10 (N.D. Ind. Oct. 8, 1998) (citations omitted) (federal False Claims Act case). Given the specificity and relatively limited number of documents sought, compliance with the Subpoenas by MBMC and MBHS will not be unreasonably burdensome. The Government has satisfied the fourth factor of the analysis.

V. The Privileges Identified by MBMC and MBHS Do Not Provide a Basis for Quashing the Subpoenas.

MBMC and MBHS argue that because the Subpoenas seek documents that MBMC and MBHS contend are protected by the attorney-client privilege, the insurer-insured privilege, and the peer review privilege, the Subpoenas must be quashed. Federal law, not Missouri state law, is controlling in federal criminal cases. Federal Rule of Evidence 501 provides that privileges "shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience." Thus, privileges recognized by Missouri state law do not protect documents from disclosure in the Government's federal criminal investigation unless the federal court determines it appropriate to apply the privilege.

The Government has already noted that where MBMC and MBHS take the position that requested documents are protected by the attorney-client privilege, MBMC and MBHS may

provide a privilege log. The Government has indicated that once it has reviewed that log, it will confer with counsel for MBMC and MBHS regarding the production of the documents reflected on the privilege log. Given the Government's position, the Court finds that the applicability of the attorney-client privilege does not provide a basis for quashing the Subpoenas at this time.

MBMC and MBHS further assert that the insurer-insured privilege provides a basis for quashing the subpoenas. MBMC and MBHS cite for the Court's consideration a single case from outside this circuit to support their position that this Court should recognize federally the insurer-insured privilege and find that privilege a sufficient basis to quash the Subpoenas. *See* Doc. [8] at 5 (citing *Thompson by Willis v. United States*, 2020 WL 3962270 (S.D. Ill. July 13, 2020)). As the Eighth Circuit has noted, federal common law recognizes a privilege only in "*rare* situations." *In re Grand Jury Subpoena Duces Tecum*, 112 F.3d 910, 918 (8th Cir. 1997) (emphasis added) (collecting cases rejecting claims of privilege, including accountancy privilege, insurer-insured privilege, adverse spousal testimony, qualified executive privilege, etc.). Further, the Eighth Circuit has previously expressly declined to recognize an insurer-insured privilege. *Petersen v. Douglas Cty. Bank & Tr. Co.*, 967 F.2d 1186, 1188 (8th Cir. 1992) ("KBS claimed injury to the principle of complete confidentiality between an insurer and its insured . . . the magistrate judge gave little weight to KBS's asserted interest in protecting these documents from disclosure and found that the creation and application of a confidentiality privilege under the facts of this case was inappropriate. We agree[.]" In view of the significant federal interest in DOJ's ability to engage in its health oversight function, and the absence of a compelling showing of harm to the parties subject to subpoena, the Court rejects the claim of insurer-insured privilege as a basis for quashing the Subpoenas.

Finally, MBMC and MBHS raise the peer-review privilege as a basis for quashing the Subpoenas in this matter. In 1990, the Supreme Court expressly declined to create a federal common law privilege to protect the disclosure of a university's peer review materials in an employment discrimination action. *Univ. of Pennsylvania v. E.E.O.C.*, 493 U.S. 182, 189 (1990). Similarly, all federal appellate courts to consider the issue have held that state peer review privileges do not apply in federal cases. *See, e.g.*, *Virmani v. Novant Health, Inc.*, 259 F.3d 284, 293 (4th Cir. 2001); *Mem'l Hosp. for McHenry Cty. v. Shadur*, 664 F.2d 1058, 1063 (7th Cir. 1981) (declining to apply the medical peer review privilege); *Agster v. Maricopa Cty.*, 422 F.3d 836 (9th Cir. 2005); *Adkins v. Christie*, 488 F.3d 1324, 1330 (11th Cir. 2007), *cert.*

denied, 552 U.S. 1131(2008). In *Agster*, rejecting the federal application of the peer review privilege, the Ninth Circuit noted that Congress had twice had the opportunity to consider providing the peer review privilege, yet explicitly declined to do so. 422 F.3d at 839. The Ninth Circuit concluded that the court was "especially reluctant to recognize a privilege in an area where it appears Congress has considered the relevant competing concerns but has not provided the privilege itself." *Id*.

Further, although MBMC and MBHS assert that the precedent identified by the Government is distinguishable from the present case, they fail to direct this Court to any decisions in which a federal appellate court has recognized the peer review privilege. In view of the compelling public interest in the prevention of healthcare fraud and the enforcement of the criminal prohibitions on healthcare fraud, this Court, like many before it, declines to recognize the applicability of the peer review privilege to the present matter.

VI. The Protections Mandated By 18 U.S.C. § 3486 and 45 C.F.R. § 164.512 Are Sufficient To Protect Any Privacy Interest in the Requested Records.

MBMC and MBHS further seek a protective order for any records produced in response to the Subpoenas, in order to protect patient privacy. As further discussed below, this Court finds that the protections already provided under the applicable statutes and regulations are sufficient to protect any privacy interest in the requested records.

As the moving parties for the protective order, MBMC and MBHS have "the burden to demonstrate good cause for issuance of the order." *Whitt v. City of St. Louis*, 2020 WL 7122615, at *15 (E.D. Mo. Dec. 4, 2020). A court may enter a protective order to prevent annoyance, embarrassment, oppression, or undue burden or expense. Fed. R. Civ. P. 26(c)(1). To show good cause, "the parties seeking protection must show that specific prejudice or harm will result if no protective order is granted." *Id.* MBMC and MBHS have not identified any specific prejudice or harm that will result if the requested protective order is not granted. In 2003, as authorized by HIPAA, the Secretary of the Department of Health and Human Services promulgated "Standards for Privacy of Individually Identifiable Health Information" (referred to herein as the HIPAA Privacy Rule), which generally prohibit the disclosure of individually identifiable medical information ("PHI") without the consent of the individual. 45 C.F.R. §164.512. However, the HIPAA Privacy Rule permits disclosure of PHI in specified circumstances, including but not limited to disclosures as required by law, disclosures for "health

oversight," disclosure to law enforcement agencies, and disclosure for use in judicial proceedings. For each permitted disclosure of PHI, the HIPAA Privacy Rule specifies the requirements for the disclosure.

Most relevant to MBMC and MBHS's Motion is 45 C.F.R. § 164.512(d), which permits the disclosure of PHI to agencies performing health oversight activities. Under this section, a covered entity[1] may disclose PHI to a health oversight agency for oversight activities authorized by law, "including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of (i) the health care system; (ii) Government benefit programs for which health information is relevant to beneficiary eligibility . . . ." DOJ acts as a health oversight agency when subpoenas are issued as part of a federal criminal investigation of federal health care fraud offenses.

The Hospitals contend that DOJ is not a health oversight agency under the relevant regulations, but they are mistaken. TDOJ has long been recognized in its capacity as a health oversight agency in connection with its investigation of allegations of healthcare fraud. In *U.S. ex rel. Stewart v. Louisiana Clinic*, No. CIV.A. 99-1767, 2002 WL 31819130, at *9–10 (E.D. La. Dec. 12, 2002), the district court explicitly rejected the defendants' request for a protective order limiting the use of nonparty patient medical and billing records obtained by the United States in a qui tam action solely to the litigation at hand. The Court further rejected a request identical to that made by MBMC and MBHS in the present matter, to wit, that the defendants "produce the documents only after all patient identifying information has been redacted." *Id.* at *1. In rejecting the requested protective order, the district court cited 45 C.F.R. § 164.512(d)(1), and noted that the "final rule implementing the Standards specifically names the Department of Justice as a health oversight agency with respect to its conduct of oversight activities relating to the health care system and its civil rights enforcement activities." *Id.* at *9 (citing 65 Fed. Reg. 82462, 82492 (Dec. 28, 2000)). The court found that the regulations permitting the disclosure of unredacted information to health oversight agencies, such as DOJ in the present matter, were

[1] A "covered entity" is a health care provider that transmits electronic information, a health plan, and a health care clearinghouse and their business associates. 45 C.F.R. § 160.103. DOJ is not a covered entity.

"clear and unambiguous, and they wholly undermine defendants' arguments to the contrary." *Id.* at *10.

Similarly, in *U.S. ex rel. Kaplan v. Metro. Ambulance & First-Aid Corp.*, 395 F. Supp. 2d 1, 5 (E.D.N.Y. 2005), the district court, rejecting a requested protective order, observed that "[t]he United States Department of Justice is a health oversight agency as defined in this regulation." (citing 45 C.F.R. § 164.501). Noting DOJ's role as a health oversight agency, the *Kaplan* court, like the *Stewart* court, held that "the protective order may not restrict the government's use of confidential patient medical records solely to purposes of this litigation." *Id*.

Likewise, § 164.512(e)(1)(ii), cited by MBMC and MBHS, is not applicable to administrative subpoenas issued by DOJ in its health oversight role. Section 164.512(e) entitled "Standard: Disclosures for judicial and administrative proceedings," provides that a covered entity may disclose protected health information in the course of any judicial or administrative proceeding in response to an order of a court or administrative tribunal, a subpoena, discovery request, or other lawful process if the covered entity receives satisfactory assurance that notice has been given to the patient or reasonable efforts have been made to obtain a qualified protective order. *See* 45 C.F.R. § 164.512(e)(1). However, § 164.512(e)(2) states that "[t]he provisions of this paragraph [Section 164.512(e)] do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information." Thus, § 164.512(e)(1)(ii) does not enlarge the requirements for disclosure authorized under § 164.512(d) for health oversight activities, and a covered entity is permitted to disclose de-identified information to DOJ, when DOJ is carrying out health oversight activities. Therefore, MBMC and MBHS's motion for a protective order will be denied.

MBMC and MBHS also seek an order requiring the return or destruction of the documents upon the conclusion of the investigation. The Government has indicated in its responsive memorandum that the Government will return any original documents when the investigation, any possible prosecution, and related post-conviction proceedings are completed. Therefore, MBMC and MBHS's request for an order requiring return or destruction of documents is denied as moot.

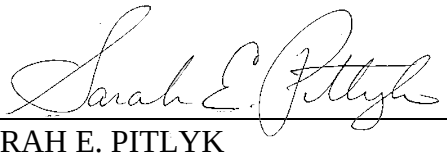
Accordingly,

IT IS HEREBY ORDERED that the Joint Motion of MBMC and MBHS to Quash the Administrative Subpoenas (Doc. [1]) is **DENIED**.

IT IS FURTHER ODERED that the Joint Motion of MBMC and MBHS for a Protective Order is **DENIED.**

IT IS FINALLY ORDERED that the request of MBMC and MBHS for an Order requiring destruction or return of records is **DENIED as moot.**

Dated this 2nd day of June, 2022.



SARAH E. PITLYK
UNITED STATES DISTRICT JUDGE